DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 31, 2016

Regulatory Technology Services LLC
c/o Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
Buffalo, MN 55313

Re: K103459
Trade/Device Name: Vascutrak™ PTA Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: PNO
Dated: November 23, 2010
Received: November 24, 2010

Dear Mr. Job:

This letter corrects our substantially equivalent letter of December 13, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Misti L. Malone -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

DEC 13 2010

510(k) Number (if known): K103459

Device Name: Vascutrak™ PTA Dilatation Catheter

Indications for Use: The Vascutrak™ PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arterioveneous dialysis fistulae. This device is also recommended for post-dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103459

Vascutrak™ PTA Dilatation Catheter

510(k) Summary
21 CFR 807.92

DEC 1 3 2010

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a 510(k) summary upon which substantial equivalence determination is based is as follows:

Submitter Information:

Applicant: Bard Peripheral Vascular, Inc
1625 West 3rd Street
Tempe, Arizona 85281

Phone: 480-303-2662

Fax: 480-449-2546

Contact: Candace Wade, Regulatory Affairs Associate

Date November 4, 2010

Subject Device Name:

Device Trade Name:	**Vascutrak™ PTA Dilatation Catheter**
Common or Usual Name:	Percutaneous Catheter (21 CFR 870.1250, Product Code DQY)
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Devices:

- Vascutrak™ 2 PTA Dilatation Catheter (K082343; cleared September 11, 2008)
- Conquest™ PTA Balloon Dilatation Catheter (K083657; cleared December 24, 2008)
- Dorado™ PTA Balloon Dilatation Catheter (K072283; cleared September 19, 2007)

Device Description:

The Vascutrak™ PTA Dilatation Catheter is composed of a flexible shaft with a semi-compliant balloon fixed at the distal end and a 0.018" or 0.014" guidewire lumen through the distal tip. The catheter shaft contains an inflation lumen that begins at the proximal female luer lock hub and ends in the proximal portion of the balloon. The proximal portion of the shaft is comprised of a stainless steel tube while the distal portion of the shaft contains a stainless steel core wire that parallels the inflation lumen, exits the shaft proximal to the balloon and terminates distal to the balloon. The distal portion of the catheter shaft has a hydrophilic coating for lubricity. Two radiopaque marker bands located on the outer core wire delineate the working length of the balloon to aid in balloon placement. Packaged with every product is a profile reducing sheath that is positioned over the balloon for protection before use.

Attribute	Vascutrak PTA Dilatation Catheter Product Offering	
	0.014" Configuration	0.018" Configuration
Balloon Diameter (mm)	2, 2.5, 3, 3.5	4, 5, 6, 7
Balloon Length (mm)	20, 40, 60, 80, 100, 120, 150, 200, 250, 300	20, 40, 60, 80, 100, 120, 150, 200, 250, 300
Catheter Shaft Lengths (cm)	140	80, 140
Introducer Sheath Compatibility (compatible balloon diameters, mm)	5F: (2, 2.5, 3, 3.5)	5F: (4) 6F: (5) 7F: (6, 7)

Indications for Use of Device:

The Vascutrak™ PTA Dilatation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arterioveneous dialysis fistulae. This device is also recommended for post-dilatation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature.

Comparison of Indications for Use to Predicate Devices:
The indication for use statement for the Vascutrak™ PTA Dilatation Catheter does not raise any new issues of safety and effectiveness as demonstrated through the risk analysis process based on the proposed indications for use statement as compared to the predicate devices, the Vascutrak™ 2 PTA Dilatation Catheter, the Conquest™ PTA Balloon Dilatation Catheter, and the Dorado™ PTA Balloon Dilatation Catheter. Therefore, the subject device, the Vascutrak™ PTA Dilatation Catheter, is substantially equivalent to the predicate devices.

Technological Comparison to Predicate Devices:
The Vascutrak™ PTA Dilatation Catheter has the following similarities to the predicate devices:

- Similar intended use (all predicates)
- Similar indications for use (all predicates)
- Same target population (all predicates)
- Same fundamental scientific technology (all predicates)
- Same operating principle (all predicates)
- Same packaging materials and configuration (Vascutrak 2 PTA Dilatation Catheter)
- Same sterility assurance level and method of sterilization (all predicates)

Performance Data:
To demonstrate substantial equivalence of the subject device, the Vascutrak™ PTA Dilatation Catheter to the predicate devices, the technological characteristics and performance criterion were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Assessment procedures, the following *in vitro* tests were performed:

- Puncture Resistance
- Robustness

The results from these tests demonstrate that the technological characteristics and performance criteria of the Vascutrak™ PTA Dilatation Catheter are comparable to the

predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusions:
The subject device, the Vascutrak™ PTA Dilatation Catheter, met all the predetermined acceptance criteria of design verification and validation as specified by applicable standards, guidance, test protocols and/or customer inputs. The Vascutrak™ PTA Dilatation Catheter is substantially equivalent to the legally marketed predicate devices, the Vascutrak™ 2 PTA Dilatation Catheter, the Conquest™ PTA Balloon Dilatation Catheter, and the Dorado™ PTA Balloon Dilatation Catheter.